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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,120	11/30/2001	Marie-Christine Missana	P21742	8264

7055 7590 04/02/2003

GREENBLUM & BERNSTEIN, P.L.C.
1950 ROLAND CLARKE PLACE
RESTON, VA 20191

EXAMINER

ISABELLA, DAVID J

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/02/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

11

1	Application No.	Applicant(s)	
	09/980,120	MISSANA ET AL.	
Office Action Summary	Examiner	Art Unit	
	DAVID J ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-75 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Amendment Before First Office Action

Preliminary Amendment filed on 5/9/02 was not filed along with the original application and therefor does not enjoy the status of part of the original disclosure. See MPEP 714.09

Drawings

The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on May 9, 2002 have been disapproved because they introduce new matter into the drawings. 37 CFR 1.121(f) states that no amendment may introduce new matter into the disclosure of an application. The original disclosure does not support the showing of the character lines to x', and alpha'.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24,25,27,32-36,41,42,48-63,74 and 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The original specification as filed fails to provide support for the claims as is now amended. Listed below are some illustrative examples. It is applicant's responsibility to review the original specification and point out support for all changes in the current amendments to the specification.

Changes to the paragraphs beginning on line 8 of page 5 contains subject matter that is not clearly supported by the original specification. See, appendix 5, page 34, lines 6-12, lines 13-22; page 35, lines 1-10, lines 11-21,22-27; appendix 7, lines 3,5,14,15; appendix 8, lines 3,4,5,6; and appendix 9, line 5.

Contrary to applicant's arguments, applicant has failed to provide a statement that the amendment of 5/9/02 contains no new matter. Accordingly, the claims and drawings that correspond to the amendment to the specification fails to find support.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite. Line 4 change "comprising" to --having--. Lines 8 and 9 are redundant.

Claim 23 fails to further define the prosthesis of claim 22. Claim 22 does not positively set forth the filling material in the body of the claim.

Claim 25 fails to define the first and second distances.

Claim 26 is redundant.

Claim 28 should be reworded as --no greater than 0.95--.

Claim 32 is meaningless.

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Claim 33, see rejection to claim 32 supra.

Claim 34 fails to define the fourth and fifth distances.

Claim 35 is redundant.

Claim 37 is redundant.

Claim 41 is meaningless. What constitutes an overlap portion.

Claims 42-47, see rejection to claim 41 supra.

Claim 48, it is not clear what is being claimed. If the surface is concave, then it is curved.

Claim 49, see rejection to claim 48 supra.

Claim 50, see rejection to claim 48 supra.

Claim 51, it is not apparent how one is to determine a point that is farthest from the plane extending through the edge of the inner zone and the edge of the outer zone.

Claim 52, see rejection to claim 51 supra.

Claim 53, see rejection to claim 48 supra

Claim 54, see rejection to claim 48 supra.

Claims 55-57, see rejection to claim 51 supra.

Claim 58, see rejection to claim 48 supra.

Claims 59-60, see rejection to claim 51 supra.

Claim 61, it is not clear what constitutes "another portion".

Claim 62 is meaningless.

Claim 73 is meaningless.

Claim 74, see rejection to claim 22 supra.

Claim 75, the nipple zone as defined is indefinite. It is not clear how each parts have different volumes.

Contrary to applicant's arguments, the rejections are not made based upon breadth of the claims. It is clear that the claims are indefinite as per the previous office action.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-75 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schweikhart (GB 2146692).

The claims attempt to define zones and distances obliquely. Since the claims fail to specifically locate the various zones, points and between edges, the examiner may interpret any zones, points and between edges that would meet the broadness of the claimed limitations. Since Schweikhart discloses a prosthesis having the angles as claimed, then the zones, points, planes and distances between various edges and arbitrary points are inherent in the structure of Schweikhart. The language of the claim "which is specific to either a right breast side or left breast side" does not preclude the breast prosthesis as disclosed by Schweikhart. Applicant narrow interpretation of the reference does not support the language of the claims. The claim fails to positively define that the breast prosthesis is assymetrical which is specific to either a right side or left side. As broadly worded, the claims do not preclude the prosthesis of Schweikhart.

With respect to applicant's arguments directed to the lack of the disclosure of a "soft pouch", examiner directs applicant's attention to page 1, lines 68-75, page 2, lines 20-35 and Figure 4. Applicant's arguments are not commensurate with the broad scope of the claims. As to applicant's arguments directed to Schweikhart failure to disclose an implantable breast prosthesis, the argument is not well taken. The implant of Schweikhart, though serving a temporary function, does provide the function of augmenting the tissues and therefor may be considered a prosthetic device.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DAVID J ISABELLA** whose telephone number is 703-308-3060. The examiner can normally be reached on **MONDAY-FRIDAY**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **CORRINE MCDERMOTT** can be reached on 703-308-2111. The fax

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phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

dji
March 27, 2003